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TOWNSEND and TOWNSEND and CREW LLP

By: All'M SS:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERANCES

In re application of:

CHERNYAK, DIMITRI A. et al.

Application No.: 10/808,728

Filed: March 24, 2004

For: CALIBRATING LASER BEAM POSITION AND SHAPE USING AN

IMAGE CAPTURE DEVICE

Confirmation No. 5629

Examiner: David M. Shay

Technology Center/Art Unit: 3735

APPELLANTS' BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief Commissioner for Patents P.O. Box 1450 Alexandria. VA 22313-1450

Sir:

Further to the Notice of Appeal mailed on December 18, 2009 for the abovereferenced application, and further to the Amendment filed on June 17, 2010, Appellants submit this Brief on Appeal.

Appendix A, attached hereto, contains a copy of all claims pending in this case.

Appendix B, attached hereto, is marked as the evidence appendix. Appendix C, attached hereto, is marked as the related proceedings appendix.

TABLE OF CONTENTS

1. REAL PARTY IN INTEREST
2. RELATED APPEALS AND INTERFERENCES
3. STATUS OF CLAIMS
4. STATUS OF AMENDMENTS
5. SUMMARY OF CLAIMED SUBJECT MATTER 4
6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL7
7. ARGUMENT
8. CONCLUSION
9. CLAIMS APPENDIX17
10. EVIDENCE APPENDIX22
11 RELATED PROCEEDINGS APPENDIX 23

1. REAL PARTY IN INTEREST

All right, title and interest in the subject invention and application are assigned to AMO Manufacturing USA, LLC, having offices at 1700 E. St. Andrew Place, Santa Ana, CA 92705-4933. Therefore, AMO Manufacturing USA, LLC is the real party in interest.

2. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-32 were originally presented in the subject application. Claims 1-32 are pending and are the subject of this appeal. Claims 1, 15, 23 and 24 are independent claims. Claims 1-14, 16-24, and 26-32 have been rejected under 35 U.S.C §103(a) as being allegedly unpatentable over U.S. Patent No. 6,116,737 issued to Kern (hereinafter "Kern") in combination with U.S. Patent Publication. US2002/0077622 to Hofer (hereinafter "Hofer") and U.S. Patent No. 4,732,148 issued to L'Esperance, Jr. (hereinafter "L'Esperance"). Claim 15 has been rejected under §103(a) as being allegedly unpatentable over Kern in view of Hofer and L'Esperance, and further in view of U.S. Patent No. 6,404,457 issued to Noh (hereinafter "Noh"). Claim 25 has been rejected under §103(a) as being allegedly unpatentable over Kern in view of Hofer and L'Esperance, and further in view of U.S. Patent No. 5,782,822 issued to Telfair et al. (hereinafter "Telfair"). As indicated by the Final Office Action of September 18, 2009, all pending claims stand rejected.

4. STATUS OF AMENDMENTS

A Notice of Appeal was filed on September 18, 2009. In the Amendment filed on June 17, 2010, claims 8 and 30 were amended. A copy of all the pending claims involved in the appeal, including the amendments filed on June 17, 2010, is provided in the attached Appendix A.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The appealed claims are directed toward methods and systems for calibrating laser pulses from a laser eye surgery system. These systems and methods generally take advantage of microscope structures that have long been included with laser surgical systems. However, rather than merely visually monitoring the eye surface during an ongoing surgery, the microscope can instead help calibrate the laser system before the surgery, typically through the use of an optical image processing system and a simple calibration target that is temporarily positioned at the eye treatment plan. More specifically, an exemplary laser eye surgery system (10) generally has an image capture device (20) oriented for imaging an eye during laser eye surgery. [Fig. 1, page 7, para. 31 of the subject application (hereinafter "subject application")]. A pulsed laser beam (26) of the laser eye surgery system (10) is directed onto a calibration surface so as to leave a mark (28) on the calibration surface (18), such as by using a calibration surface that is discolored by the laser, that fluoresces in response to the laser, or the like. [Id. at pages 7-8, paras. 31-321 The image capture device (20) images the mark (28) and also images a known object (30), with the known object often comprising a simple high-contrast circle disposed at the treatment plane. [Id., see also Figs. 2 and 9A] The imaged mark and object each have an imaged size, shape and location. [Id. at pages 4-5, paras. 13-14, and page 9, para. 35] A laser beam cross-sectional shape, location and/or size of the laser eye surgery system can be calibrated by comparing the image of the mark (28) to that of the known object (30). [Id. at page 3, para. 9 and pages 14-15, paras. 46-47]

The image-processing based laser eye surgery calibration techniques of the present invention can, for example, help both quantify and compensate for a subtle (and apparently, previously unrecognized within the laser eye surgery field) source of laser surgical error: variable aperture hysteresis. Specifically, the use of the image of the known object (30) allows the magnification of the image capture device (20) to be quantified (generally by applying a fitting routine to the optical image data of the mark (28) and the known object (30)) so as to accurately and precisely measure and calibrate the laser beam cross-sectional size. [Id. at page 3, para. 9, page 9, para. 35 and page 14, para. 46] By comparing the imaged object size with the imaged mark size, a relationship between laser beam diameter and motor counts associated with

a variable aperture (116) of the laser eye surgery system can be determined. Further, the diameter setting of the pulsed laser beam (26) can be increased over time and then decreased over time, forming a plurality of marks. These marks are imaged, and any hysteresis (such as variability in measured sizes of the aperture related to prior aperture sizes) can be determined and accounted for. [Id. at Figs. 8A, 8B and 9B, page 3 para. 9, pages 12-13, paras. 41-42, and page 15, para. 47] Although small, because the amount of hysteresis can be significant to the desired precision associated with corrections to the optics of a patient's eye, separate calibration data for an increasing aperture and a decreasing aperture may enhance the accuracy of laser ablations. [Id. at Figs. 8A, 8B and 9B, page 3 para. 9, pages 12-13, paras. 41-42, and page 15, para. 47, for example]

As recited in independent claim 1, a method for calibrating laser pulses from a laser eye surgery system (10) is disclosed. The laser eye surgery system (10) has an image capture device (20) oriented for imaging an eye during laser eye surgery. [Id. at Fig. 1, page 7, para. 31]. A known object (30) is imaged with the image capture device (20). [Id., see also Fig. 2 and page 9, para, 35 and Fig. 9A and pages 14-15, paras, 46-47] The imaged object has an imaged object size, an imaged object shape, and an imaged object location. [Id. at pages 4-5, paras, 13-14, and page 9, para, 35] A pulsed laser beam (26) of the laser eye surgery system (10) is directed onto a calibration surface so as to leave a mark (28) on the calibration surface (18). [Id. at pages 7-8, paras. 31-32] The image capture device (20) images the mark (28) with the image capture device (20). The imaged mark has an imaged mark size, imaged mark shape, and imaged mark location. [Id. at pages 4-5, paras. 13-14, and page 9, para. 35] A laser beam crosssectional shape, location and/or size of the laser eye surgery system is calibrated by comparing the image of the mark (28) on the calibration surface to the image of the known object (30). [Id. at page 3, para. 9 and pages 14-15, paras. 46-47]. Claims 2-14 and 16-22 depend directly or indirectly from claim 1 and are allowable as depending from an allowable claim and reciting additional novel combinations of claim elements.

As recited in independent claim 15, a method for calibrating laser pulses from a laser eye surgery system (10) using an image capture device (20) is also disclosed. A known objection (30) is imaged with the image capture device (20). A pulsed laser beam (26) is

directed onto a calibration surface (18) so as to leave a mark (28) on the calibration surface. [Id. at Fig. 1 and pages 7-8, paras. 31-32] The diameter setting of the pulsed laser beam (26) is increased over time with a variable aperture (116) so as to form a plurality of marks (28), which are imaged and compared with the known object (30). The diameter setting of the pulsed laser beam (26) can then be decreased over time with the variable aperture (116). The laser eye surgery system (10) is calibrated by comparing the image of the mark on the calibration surface to the image of the known object (30). The calibration of the laser eye surgery system comprises determining a hysteresis of the variable aperture (116). [Fig. 3 and page 7, para. 30].

As recited in independent claim 23, a method for calibrating laser pulses from a laser eye surgery system (10) having a microscope camera (20) is also disclosed. A known object (30) is imaged with the microscope camera (20) oriented toward an eye treatment plane of the laser eye surgery system. The imaged known object (30) has a known object size. A pulsed laser beam (26) is scanned across a photosensitive material disposed along the eye treatment plane so as to leave an ablation on the photosensitive material. The ablation on the photosensitive material is imaged with the microscope camera (20), while the photosensitive material is disposed along the eye treatment plane. The imaged ablation has an ablation size. [Id. at Figs. 1 and 2, pages 7-8, paras. 31-32, page 11. para. 38, and pages 11-12, para. 39] An iris calibration of the laser eye surgery system is determined by comparing the ablation size in the image of the ablation on the photosensitive material to the known object size in the image of the known object. [Id. at pages 12-15, paras. 40-47] A patient's cornea is ablated with the calibrated system (10). [Id. at pages 8-9, para. 34 and pages 10-11, para. 37].

As recited in independent claim 24, a system for calibrating laser pulses (26) from a laser system (10) is also disclosed. The system comprises an image capture device (20), a known object (30), a pulsed laser beam delivery system (10), a calibration surface (18), and a processor (22). [Id. at Fig. 1 and page 7, para. 31] The image capture device (20) is oriented toward a treatment plane. The known object (30) is positionable for imaging by the image capture device (20). The pulsed laser beam delivery system (10) is oriented for directing a pulsed laser beam (26) toward the treatment plane. The calibration surface (18) is supportable in an optical path (32) of the pulsed laser beam (26) so as to result in a mark (28) on the calibration

surface and for imaging of the mark (28) on the calibration surface by the image capture device (20). The processor (22) is coupled to the image capture device (20) and determines a calibration of the laser beam delivery system (10) by comparing the image of the mark (28) on the calibration surface (18) to the image of the known object (30). [Id. at pages 7-8, paras. 31-32]. Claims 25-32 depend directly or indirectly from claim 24 and are allowable as depending from an allowable claim and reciting additional novel combinations of claim elements.

As can be understood with the above summary and with reference to the subject application, for example, from pages 2-3 at paragraphs 6-9 of the subject application, the claimed systems and methods provide a relatively simple, low cost, and yet highly accurate and precise laser beam cross-sectional size, shape, and/or location calibration. Moreover, these techniques can be applied through a novel use of an existing piece of equipment—a microscope—that is already included in a wide variety of laser eye surgery systems, but which has not previously been employed to provide such laser calibration data.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether or not claims 1-14, 16-24, and 26-32 have been shown to be unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,116,737 issued to Kern (hereinafter "Kern") in combination with U.S. Patent Publication. US2002/0077622 to Hofer (hereinafter "Hofer") and U.S. Patent No. 4,732,148 issued to L'Esperance, Jr. (hereinafter "L'Esperance").
- B. Whether or not claim 15 has been shown to be unpatentable under §103(a) over Kern in view of Hofer and L'Esperance, and further in view of U.S. Patent No. 6,404,457 issued to Noh (hereinafter "Noh").
- C. Whether or not claim 25 has been shown to be unpatentable under §103(a) over Kern in view of Hofer and L'Esperance, and further in view of U.S. Patent No. 5, 782, 822 issued to Telfair et al. (hereinafter "Telfair").

7. ARGUMENT

A. Rejection of claims 1-14, 16-24, and 26-32 under 35 U.S.C. §103(a):

In the Office Action of September 18, 2009, claims 1-14, 16-24, and 26-32 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kern in combination with Hofer and L'Esperance.

Claims 2-14, and 16-22 depend from independent claim 1. Claims 26-32 depend from independent claim 24. Independent claims 1, 23 and 24 share many related limitations. A known object is imaged with an image capture device or a microscope, a pulsed laser beam is directed onto or scanned over a calibration surface so as to leave a mark or ablation, the mark or ablation is imaged with the image capture device, and the laser beam is calibrated by comparing the imaged known object with the imaged mark or ablation.

Per the preamble of claim 1, that claim recites a "method for calibrating laser pulses from a laser eye surgery system, the laser eye surgery system having an image capture device oriented for imaging an eye during laser eye surgery." Per the body of claim 1, the claimed invention is limited to methods in which "imaging a known object" and "imaging the mark on the calibration surface" are both performed using this specific image capture device of the laser eye surgery system. Per claim 1, calibrating a laser beam shape, location, and/or size is performed using these images—obtained by the same image capture device that is oriented toward the eye for imaging during surgery. Hence, per the method of claim 1, the measurements for the claimed calibration must be performed using the same image capture device that is oriented for imaging the eye during surgery. Advantageously, individual (or small groups of) laser pulses of different size, location, and/or shape may be compared to the known object and used for efficient correction of specific aspects (variable aperture, scanning optics, etc.) of these sophisticated laser eye surgery systems without having to resort to separate and expensive measurement devices.

The preamble of claim 23 similarly recites a "method for calibrating laser pulses from a laser eye surgery system having a microscope camera." The body of claim 23 recites a method in which imaging of a known object is performed with the camera oriented toward the eye treatment plane and imaging of an ablation on a photosensitive material is performed with this same microscope camera with the photosensitive material disposed along the eye treatment plane. An iris calibration of the laser eye surgery system is then determined using these images.

Per the body of system claim 24, an image capture device is oriented toward a treatment plane, and a known object is positionable for imaging by that image capture device. Claim 24 also specifies that a calibration surface is supportable so that a laser results in a mark, and for imaging of that mark by the image capture device. A processor of claim 24 determines a calibration of the laser beam delivery system by comparing the image of the mark to the image of the known object, thereby again making use of an image capture device appropriately oriented for imaging the eye during surgery so as to also provide laser calibration. By using these existing image capture devices, adjustment factors can be derived directly for altering an iris motor command, a scan motor command, or the like.

Under 35 U.S.C. §103(a), a patent may not be obtained if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. [M.P.E.P. §2141] The Supreme Court in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), clarified that a rejection under §103 requires that the scope and contents of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and that the level of ordinary skill in the art be resolved. Secondary considerations such as commercial success, long-felt but unresolved need, failure of others, etc. must also be evaluated.

First addressing the scope and contents of the prior art, Kern relates to the creation of an ablative profile, which is measured and compared with an intended ablative profile so as to allow for adjustment of an ablative laser's parameters (col. 1, ln. 12-22; col. 2, ln. 66 - col. 3, ln. 18). In the Kern approach, a specially formulated collagen material having an ablation rate approximately equal to that of corneal tissue is ablated (col. 2, ln. 32-38). The surface profile or shape of the ablation is measured with a surface profiling instrument, preferably a non-contact interferometer (see Kern: col. 3, ln. 43-54; col. 4, ln. 29-42). The Kern methodology then seeks to confirm or adjust the operating parameters of the laser system based on the surface shape profile measurements (see Kern: col. 3, ln. 51-53). Thus, Kern indicates that the laser system is to be calibrated by first forming an ablation profile or shape in an artificial cornea, and if a surface shape measurement indicates any overall inaccuracies, by then

seeking to identify the source of the error. As it can take hundreds or even thousands of individual pulses to form the Kern ablation profile, there is no indication how the Kern technique could be used, for example, to measure individual pulse locations that are slightly off-set so as to allow correction of a scan motor non-linearity. There is also no indication in Kern that suitable calibration measurements could instead be obtained by an image capture device oriented so as to image the eye during surgery.

Hofer relates to a system that verifies the scanning motion of a laser beam during treatment of an eye. (See Hofer, Abstract). Per Hofer, a beam splitter 230 splits the laser beam into a primary beam 232 directed towards the surgical area of the eye E, and a secondary beam 234 directed toward a position verification detector or motion sensor 240. (Hofer, para. 23; Fig. 2). The motion detector has a photosensitive surface and a mask at least partially covering the photosensitive surface. The motion detector is thereby adapted to vary the exposure of the photosensitive surface to laser energy so as to register different energy readings as the beam is moved laterally across the surface. (Hofer, para. 9) "Laser beam position feedback information is provided and compared with expected results. Should the feedback information be inconsistent with the expected results, the procedure is typically interrupted." (Hofer, para. 7). Hence, Hofer provides a laser scan verification system that is entirely separate from any microscope camera oriented for imaging the eye, and which instead relies on splitting the beam during surgery and directing a portion of the treatment beam away from the eye and toward a mask/photodetector unit during surgery. Replacing the eye with a calibration surface at the eye treatment plane as now claimed would be incompatible with the intended function of the Hofer system, as the system would no longer be able to verify beam scanning movement during treatment of the eye itself.

L'Esperance relates to devices and techniques for surgically operating upon the outer surface of the cornea (see L'Esperance: col. 1, ln. 62-64). An apparatus effectively fixes the position of an eye with respect to what appears to be a non-scanning laser, and a sculpturing action upon the outer surface of the cornea results from the controlled change of the projected laser spot size over the course of a treatment (see L'Esperance: col. 2, ln. 13-28). The laser spot size is changed through the use of a zoom lens, an indexible mask, or an indexible mirror (see

L'Esperance: col. 2, ln. 28-35). While the L'Esperance reference may disclose a significant and historic advancement in the field, the reference simply does not appear to identify any calibration techniques that could, for example, identify, measure, and correct scan motor non-linearities.

Moving on to address the differences between the prior art and the claims at issue, Appellants note that numerous elements of claims 1-14, 16-24, and 26-32 are not disclosed by Kern, Hover, or L'Esperance, or by any reasonable combination of all three. None of the cited reference discloses the currently claimed imaging of a known object with a microscope or image capture device oriented for imaging the eye during surgery. As can be understood from the above, this use of a known object greatly contributes to the precision with which the microscope can optically identify and quantify a location, size, and/or shape of an individual beam pulse (or small group of pulses) at the eye treatment plane. Also, none of the three cited references discloses comparing the image of the known object with the image of a mark on a calibration surface to calibrate the shape, location and/or size of a laser beam. Although Kern may disclose the goal of calibrating a laser system, the Kern calibration is based on interferometer measurement of the depth profiles of ablation made on a sample material. Hence, no image from an eye-treatment plane is used whatsoever in the Kern calibration, much less are such images compared with images of a known object taken by the same image capture device. Moreover, measurement of an ablated surface shape by even a specialized and expensive interferometer would not as readily or directly provide the cross-sectional shape, location and size of the laser beam. In contrast, size, shape, and/or location of a scanned beam pulse are directly available using the methods of claims 1-23 and systems of claims 24-32. Hofer is intended for use during laser treatment of the eye by splitting the treatment beam and measuring a portion of the laser energy in a structure separated from the eye treatment plane. L'Espereance does not disclose the calibration of any laser system, much less the imaging of a known object and comparing that imaged object with an imaged laser pulse mark using a treatment monitoring microscope. Therefore, Kern, Hofer, and L'Esperance, alone or in combination, fail to disclose each and every element of the claims at issue. For at least this reason, the claims at issue are allowable over Kern, Hofer, and L'Esperance.

In a standard Graham analysis, the level of ordinary skill in the art must also be resolved and secondary considerations must also be considered. The inventions claimed in the subject application include methods and systems pertaining to calibrating laser pulses particularly from laser eye surgery systems. Thus, persons of ordinary skill in the art would likely be able to understand the primary concepts disclosed in the Kern, Hofer, and L'Esperance references, and might well be familiar with devices (and their related methods of use) that were widely in use in the field at the time the subject application was filed. Such a skilled artisan might understand both the advantages and disadvantages of non-contact interferometers as described in Kern and the laser eye surgery devices described by L'Esperance, as such devices and methods significantly pre-date the time the claimed invention was made (L'Esperance having issued in 1988 and Kern in 2000, while the subject application was filed in 2004). Similarly, those of skill in the art would also recognize the benefits of using Hofer's beam position verification system during laser treatment of the eye. Modification of the system actually described by Hofer by eliminating the beam splitter and moving the Hofer mask and photodetector to the eye treatment plane would preclude the beneficial use of Hofer's system for its intended purpose, and would still fail to make use of the eye-viewing microscope included in many laser eye surgery systems. Yet, the relatively simple, cost effective, and highly advantageous methods and systems of the present invention (including calibrating laser beam size, shape, and/or location by comparing an image of a laser beam mark and an image of a known object, where both images are obtained using an eye treatment-monitoring microscope) has not been shown prior to the present invention. In fact, based on the cited references, the trend in the field and in the related industry appears to be away from the use of such a straightforward method. Kern, for example, teaches the use of separate and more complex surface profiling instruments such as a non-contact interferometer. Thus, the present invention solves the long felt but unsolved need for providing a simple and straightforward method of precisely and accurately calibrating laser beam size, shape, and/or location.

Appellants note that the Office Action of September 18, 2009, on page 4, acknowledges that no reference cited against the pending claims describes imaging of a known object and using that image, together with an image of a mark or ablation formed using the laser,

to calibrate the laser. (Office Action of 9/18/2009, page 4 ("It would have been obvious to the artisan of ordinary skill to employ an image of a separate [known] object, rather than the image of the unablated calibration surface as the standard to which the ablated calibration surface is compared, since this is not critical, is well within the skill of one having ordinary skill in the art; and provides no unexpected result.") Appellants respectfully submit that the claimed use of a known object allows calibration to be performed using a standard laser eye surgery microscope, significantly enhancing calibration ease and accuracy with remarkable simplicity, as can be understood with reference to paragraphs 11, 13, 43, etc. of the originally filed specification. Disregarding this elegant and advantageous aspect of the claimed systems and method is improper, so that prima facie obviousness of the claimed invention, including the claimed use of an image of a known object, has not been established.

For the reasons set forth above, claims 1-14, 16-24, and 26-32 (and, in fact, all of pending claims 1-32) are allowable over the combination of Kern, Hofer, and L'Esperance. Appellants respectfully request the rejections be overturned for the claims at issue.

B. Rejection of claim 15 under 35 U.S.C. §103(a):

Independent claim 15 also has many limitations similar to those of independent claims 1, 23 and 24, as described above. Thus, for at least the reasons discussed above with reference to claims 1-14, and 16-32, claim 15 is allowable over the combination of Kern, Hofer, and L'Esperance.

Claim 15 further recites increasing and decreasing the pulsed laser beam diameter setting with a variable aperture and that the calibrating of the laser eye surgery system comprises determining a hysteresis of the variable aperture. Although Kern discloses a method for calibrating an ablation, increasing and decreasing the diameter of the laser beam with a variable aperture is not remotely disclosed. Kern also does not even remotely disclose determining a hysteresis of a variable aperture. Hofer discloses a laser eye system having an iris motor 116, but fails to recognize the existence of hysteresis of a variable aperture, and certainly does not describe or suggest that the laser system can or should be calibrated by determining hysteresis of that iris. L'Esperance does not disclose a calibration method but does discloses the use of a variable aperture and indexible masks or mirrors. Yet, L'Esperance also fails to disclose

determining a hysteresis of the variable aperture, much less even appreciate that hysteresis may be present in the variable aperture and indexible masks or mirrors.

Appellants also note that the use of variable apertures is well known to those of ordinary skill in the art well before the claimed invention was made. L'Esperance discloses the use of a variable aperture and was issued in 1988. Yet, determining a hysteresis of the variable aperture by comparing the image of a mark to the image of a know object does not appear to have been recognized as having any relevance to laser eye surgery until the present invention. In fact, the presence and potential impact of hysteresis in a variable aperture laser eye surgery system does not appear to have ever been appreciated until the present invention. As shown in Figs. 8C and 8D and described at page 4, paragraph 13 and pages 11-12, paragraph 41-42 of the subject application's specification, such hysteresis and any associated non-linearity may be very small and may even remain completely hidden if one was not specifically looking for them. However, the present application recognizes that such hysteresis and the associated non-linearity in laser eye surgery system can (and ideally should) be accounted for so that they do not impose a slight (but potentially significant) error in ablation shapes imposed on test articles and eyes of patients.

In a reference directed to a very different art field—movie camera shutters—the Noh patent discloses that iris hysteresis may impact operation of shutter speed control systems. (see Noh, abstract; Figs. 3 and 4; col. 2, line 60-col. 3, line 25) No laser beam is apertured using the iris of the Noh movie camera. Perhaps even more important, Noh does *not* calibrate the movie camera (or any other system) by determining hysteresis of an iris or other variable aperture. To the contrary, Noh directly measures the iris opening during use, and adjusts the camera based on the measured iris opening using a feedback system. (Noh, col. 3; lines 41-54; col. 4, lines 9-21; Fig. 5, reference numeral 22) In fact, Noh explicitly teaches away from calibrating a movie camera based on determination of iris hysteresis as follows: "since the conventional automatic shutter speed control device accompanies hysteresis according to the operation voltages in opening and closing movement of the iris as shown in Fig. 3, and with deviation between sets, detection of an extent of iris opening from the operation voltage can not be corrected." (Noh, col. 3, lines 11-15 (emphasis added)) Hence, the claimed invention,

which calibrates the laser eye surgery system by increasing beam diameter with a variable aperture, decreasing the beam diameter with the variable aperture, and compare the image of a mark formed by the beam to an image of a known object, and in which the claimed calibration includes determining of hysteresis of the variable aperture, is directly contrary to the explicit disclosure of Noh.

In summary, those of skill in the art would find no basis for comparing an image of a know object to another image captured by the same image capture device based on the actual disclosure of the cited references. Moreover, those of skill in the art would not look to the movie camera speed controller of Noh so as to modify the variable laser beam aperture of the laser eye surgery systems of the other cited references, and if they did, Noh's actual disclosure would lead them away from attempting to calibrate variable beam hysteresis per the methodology of claim 15, and would instead lead them to rely on an aperture opening feedback system.

For the reasons set forth above, claim 15 is allowable over the combination of Kern Hofer, L'Esperance, and Noh. Appellants respectfully request withdrawal of its rejection

C. Rejection of claim 25 under 35 U.S.C. §103(a):

Claim 25 depends from claim 24, and thereby includes all of the elements of that system claim. Claim 25 further recites that the image capture device comprises a microscope camera. Claim 25 is rejected under §103(a) over Kern in view of Hofer and L'Esperance, and further in view of Telfair. More specifically, on page 6 the Office Action of September 18, 2009 asserts that column 7, lines 36-51 supports the rejection. For completeness, the cited portion of Telfair provides the following disclosure:

During preparation for laser surgery on the comea, the line-of-sight of the eye 70 must be aligned to coincide with the laser beam axis by two-axis lateral-translational adjustments, in a known manner, as directed by the surgeon 55. The surgeon 55 observes the eye 70 through a surgical microscope 80 and judges the degree of centration of the frontal image of the eye 70 with respect to a crosshair or other fixed reference mark indicating, as a result of prior calibration,

the location of the axis of beam 14, in a known manner. The axial location of the eye 70 is also judged by the surgeon 55 by virtue of the observed degree of focus of the image of the eye 70 relative to the previously calibrated and fixed object plane of best focus for microscope 80. Directions from the surgeon 55 allow adjustment of the axial position of the cornea of eye 70 to coincide with the plane of best focus. (Telfair, col. 7, lines 36-51 (emphasis added))

Applicants respectfully submit that the cited portion of Telfair does not support the rejection of claim 25, as this disclosure is directed to use of a previously axially calibrated microscope camera for imaging the eye during laser eye surgery. The use of a microscope camera for a very different purpose—to image a mark formed on a calibration surface, and to also image a known object so as to calibrate the laser delivery system—is not shown, much less a processor coupled to the microscope camera, in which the processor determines a calibration of the laser beam *delivery system* by comparing the image of the mark on the calibration surface to the image of the known object. Absent any showing for the structures of the known object, calibration surface resulting in a mark, and processor of claim 24, prima facie obviousness has not been established for dependent claim 25.

8. CONCLUSION

For these reasons, it is respectfully submitted that the rejections set forth in the Final Office Action mailed on March 28, 2008 should be reversed.

Respectfully submitte

Mark D. Barrish Reg. No. 36.443

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, Eighth Floor San Francisco, California 94111-3834 Tel: 650-326-2400 Fax: 650-326-2422

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9. CLAIMS APPENDIX

 (Rejected) A method for calibrating laser pulses from a laser eye surgery system, the laser eye surgery system having an image capture device oriented for imaging an eye during laser eye surgery of the eye, the method comprising:

imaging a known object with the image capture device of the laser eye surgery system, the imaged object having an imaged object size, an imaged object shape, and an imaged object location:

directing a pulsed laser beam of the laser eye surgery system onto a calibration surface so as to leave a mark on the calibration surface;

imaging the mark on the calibration surface with the image capture device of the laser eye surgery system, the imaged mark having an imaged mark size, an imaged mark shape, and an imaged mark location; and

calibrating a laser beam cross-sectional shape, a laser beam cross-sectional location, and/or a laser beam cross-sectional size of the laser eye surgery system by comparing the image of the mark on the calibration surface to the image of the known object.

- (Rejected) The method of claim 1, wherein the imaged object comprises a circular shape having a known diameter.
- 3. (Rejected) The method of claim 2, wherein the known object comprises a circular chrome layer on a glass plate.
- (Rejected) The method of claim 1, further comprising removing the known object prior to directing the pulsed laser beam onto the calibration surface.
- (Rejected) The method of claim 1, wherein the imaging of the known object and of the mark on the calibration surface is carried out in the same position.
- (Rejected) The method of claim 1, wherein the directing and imaging are carried out in the same plane.
- 7. (Rejected) The method of claim 1, wherein the directing and imaging are carried out in at least one of a laser focus plane or a treatment plane, and wherein imaging of the

known object and imaging of the mark on the calibration surface are performed along an imaging optical path coaxial with a laser optical path.

- (Rejected) The method of claim 1, wherein the calibration surface comprises photosensitive material, silkscreen material, luminescent material, or photographic material
- (Rejected) The method of claim 8, wherein the mark on the calibration surface comprises a permanent change in color or a luminescent glow.
- (Rejected) The method of claim 1, wherein the calibration surface comprises photoreactive material or polymethylmethacrylate material.
- (Rejected) The method of claim 10, wherein the mark on the calibration surface comprises an ablation.
- 12. (Rejected) The method of claim 1, wherein the mark on the calibration surface has a diameter setting in a range from about 0.65 mm to about 6.7 mm.
- 13. (Rejected) The method of claim 1, further comprising increasing the pulsed laser beam diameter setting over time so as to form a plurality of marks, imaging the marks, and comparing the marks to the known object.
- (Rejected) The method of claim 13, further comprising decreasing the pulsed laser beam diameter setting over time.
- 15. (Rejected) A method for calibrating laser pulses from a laser eye surgery system using an image capture device, the method comprising:

imaging a known object with an image capture device;

directing a pulsed laser beam onto a calibration surface so as to leave a mark on the calibration surface:

imaging the mark on the calibration surface with the image capture device;

increasing the pulsed laser beam diameter setting over time with a variable aperture so as to form a plurality of marks, imaging the marks, and comparing the marks to the known object;

decreasing the pulsed laser beam diameter setting over time with the variable aperture; and

calibrating the laser eye surgery system by comparing the image of the mark on the calibration surface to the image of the known object, the calibrating of the laser eye surgery system comprising determining a hysteresis of the variable aperture.

- 16. (Rejected) The method of claim 1, further comprising determining a relationship between laser beam diameter and motor counts associated with an iris setting of the laser eye surgery system by comparing the imaged object size with the imaged mark size.
- (Rejected) The method of claim 1, further comprising determining a shape of the laser beam by comparing the imaged object shape with the imaged mark shape.
- 18. (Rejected) The method of claim 1, further comprising determining a center position of the laser beam by comparing the imaged object location with the imaged mark location.
- 19. (Rejected) The method of claim 1, further comprising determining a drift of the laser eye surgery system by monitoring a variance in center positions for each scanned and imaged laser pulse.
- 20. (Rejected) The method of claim 1, further comprising determining a laser hearn deflection.
- (Rejected) The method of the claim 1, further comprising rotating an
 optical element along a laser delivery path and identifying a rotation-induced laser induced
 wobble from a plurality of marks.
- (Rejected) The method of claim 1, further comprising ablating a patient's cornea with the calibrated system.
- 23. (Rejected) A method for calibrating laser pulses from a laser eye surgery system having a microscope camera, the method comprising:

imaging a known object with the microscope camera oriented toward an eye treatment plane of the laser eye surgery system, the imaged known object having a known object size:

scanning a pulsed laser beam across a photosensitive material disposed along the eye treatment plane so as leave an ablation on the photosensitive material;

imaging the ablation on the photosensitive material with the microscope camera while the photosensitive material is disposed along the eye treatment plane, the imaged ablation having an ablation size:

determining an iris calibration of the laser eye surgery system by comparing the ablation size in the image of the ablation on the photosensitive material to the known object size in the image of the known object; and

ablating a patient's cornea with the calibrated system.

24. (Rejected) A system for calibrating laser pulses from a laser system comprising:

an image capture device orientated toward a treatment plane;

- a known object positionable for imaging by the image capture device;
- a pulsed laser beam delivery system oriented for directing a pulsed laser beam toward the treatment plane;
- a calibration surface supportable in an optical path of the pulsed laser beam so as to result in a mark on the calibration surface and for imaging of the mark on the calibration surface by the image capture device; and
- a processor coupled to the image capture device, the processor determining a calibration of the laser beam delivery system by comparing the image of the mark on the calibration surface to the image of the known object.
- 25. (Rejected) The system of claim 24, wherein the image capture device comprises a microscope camera.
- 26. (Rejected) The system of claim 24, wherein the known object comprises a circular chrome layer of known diameter on a glass plate.
- 27. (Rejected) The system of claim 24, wherein the known object and calibration surface are imaged in the same position.
- 28. (Rejected) The system of claim 24, wherein the known object and calibration surface are positioned in at least one of a laser focus plane or the treatment plane.
- (Rejected) The system of claim 24, wherein the laser beam delivery system comprises a laser eye surgery system.

- 30. (Rejected) The system of claim 24, wherein the calibration surface comprises photosensitive material, silkscreen material, luminescent material, photoreactive material, polymethylmethacrylate material, or photographic material.
- 31. (Rejected) The system of claim 30, wherein the mark on the calibration surface comprises an ablation, a permanent change in color, or a luminescent glow.
- 32. (Rejected) The system of claim 24, wherein the mark on the calibration surface has an iris setting in a range from about 0.65 mm to about 6.7 mm.

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10. EVIDENCE APPENDIX

None

 $\frac{PATENT}{Attorney\ Docket\ No.\ 018158-024500US}$

11. RELATED PROCEEDINGS APPENDIX

None